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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,000

02/10/2006

Paul J. Coleman

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EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

04/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,000	Applicant(s) COLEMAN ET AL.	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 7-9 have been canceled by the amendment on 02/01/2008. Claims 1-6 are pending, and will be examined on the merits.

Response to Amendment

The amendment by Applicants' representative Nicole M. Beeler dated on 02/01/2008 has been entered.

Response to Arguments/Remarks

Rejection under 35 U.S.C. §103(a)

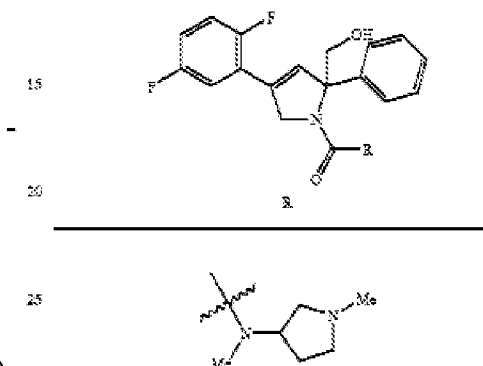
Applicant's amendment and argument over rejected claims 1-6 *under 35 U.S.C. §103(a)* have been fully considered, and are found not persuasive. Applicant's argument is on the ground that drug discovery and design is a complex process involving many variables, the pharmaceutical sciences are unpredictable, and it is difficult to predict the activity of a compound without further testing. Applicant further argued that the previously cited Patani's teaching of bioisosterism of -H vs. -F cannot be generalized for all compounds and all receptors. However, the Examiner finds the instantly claimed invention is *prima facie* obviousness over the '580 patent, and the '559 application in view of the Patani's teaching, because the Patani reference do provide the motivation for one ordinary skilled in the art to modify the prior art teachings for the instantly claimed invention, namely replace -H with -F on the very closely related prior art compound (CAS RN 686320-55-8), and the purpose for applying the prior art teaching does not need the same as the one by instantly claimed invention. More

importantly, as stated in the previous Office action, the '580 patent and the '559 application do suggest that the pyrrolidine ring as R^c can be further optionally substituted with R^{11} , wherein R^{11} as halo (i.e. Cl, Br, F, and I), as acknowledged by Applicant at page 20 under REMARKS. Applicant fails to respond to that part of analysis.

In terms of the comment on the retention of biological activity based on the *in vitro* data and *in vivo* data, it is not relevant to the instant argument because there is no *in vivo* data disclosed in the instant specification. Therefore, the Office has established *prima facie* case for obviousness over the prior art teachings. Accordingly, the rejection is maintained.

Rejection of claims 1-6 for Obviousness-type Double Patenting

Applicant's amendment and argument over rejected claims 1-6 under *Obviousness-type Double Patenting* have been fully considered, and are found not persuasive. Applicant's argument is on the ground that the '580 patent does not contain any species that overlap with the instant application. However, this argument is not found persuasive. The Examiner would like to draw Applicant's attention on the



lines 10-30 of the '580 patent, which reads on the claims in the '580 patent, and is *prima facie* obvious to the instantly claimed invention. The rationale is the same as the rejection under 35 U.S.C. § 103(a) above. Therefore, the rejection is maintained.

Claim Objections

Applicant's amendment by removal of the non-elected subject matter has obviated the objection.

Conclusions

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
Art Unit 1626

/Joseph K. McKane/
Supervisory Patent Examiner
Art Unit 1626